predetermined variables, such that when fluid flows through said hollow fiber at a predetermined velocity, Dean vortices are generated in the hollow fiber in both said first and second layers, and both first and second layers perform substantially equivalently along a predetermined performance parameter .

13. (Amended) The method of claim 12, wherein the predetermined performance parameter is predetermined algorithmically.

14. (Amended) The method of claim 12, wherein the predetermined performance parameter is predetermined empirically.

15. (Amended) The method of claim 12, wherein said variables comprise the hollow fiber's outer and inner diameter, the angle of coiling said fiber, and the length of said fiber.

16. (Amended) The method of claim 12, wherein said variables comprise the length of the mandrel and the diameter of the mandrel.

18. (Amended) The method of claim 12, wherein said hollow fiber is coiled in both steps (a) and (b) to maximize the packing density of the hollow fiber is said fiber bundle.

REMARKS

Method claims 12 to 18 are pending in this application. Claim 12 is the only independent claim. All stand rejected under 35 U.S.C § 102(b).

The claims are, in general, directed to a method for producing a "linearly scaled" multi-layered coiled hollow fiber bundle that comprises coiled hollow fiber membrane configured precisely to promote formation of Dean vortices in a fluid conducted therethrough at a predetermined fluid velocity. The method comprises the coiling of overlapping layers of hollow fiber, the coiling done according to certain predetermined variables (*e.g.*, fiber length, diameter, and coiling angle), extrapolated from a single layer device according to new algorithms disclosed herein, such that the layers perform substantially equally along a certain predetermined performance parameter (*e.g.*, flux). The accomplishment of "linear scalability" by means of assembling pre-calculated fiber configurations into multiple layers within a coiled fiber bundle -- as opposed to other means -- is unprecedented.

Claims 12 to 18 have been reviewed in light of the Office Action. Claims 12 to 15 and 18 are amended. Claims 16 and 17 are cancelled. Reconsideration is requested.

Declaration

At the outset, the examiner questioned applicants' declaration. The examiner stated that applicants' "declaration is defective", noting the "specification to which [it] is directed has not been adequately identified". Applicants appreciate the examiner's observation and acknowledge the

oversight. A corrected declaration is attached. It properly identifies the specification by the subject application's serial number (*i.e.*, 09/807,592) and filing date (*i.e.*, 05/23/2001).

Specification

The specification is amended *sua sponte* to address certain informalities, for example, to provide reference to the earlier U.S. provisional application (*i.e.,* 60/112,647) upon which the present application claims priority (*i.e.,* December 17, 1998).

Claim Rejections - 35 U.S.C. § 102

Claims 12 to 18 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Pat. No. 5,626,758, issued to G. Belfort on May 6, 1997 (*i.e.*, the "Belfort reference"). In particular, the examiner states:

> Belfort teaches a multi-layered coiled hollow fiber bundles designed to provide a specific performance output to create Dean vortices when subjected to a certain velocity wherein performance depends on the hollow fiber's inner and outer diameters, number of fibers, inherent angle of coiling and length of fibers and diameter of rod and inherently the length of the rod which fibers are coiled and minimization of gaps between fibers to inherently maximize the packing density of the fibers and above variables are calculated and manipulated to design coiled hollow fiber bundle that provide a specific performance output to create Dean Vortices.

(Citations omitted.)

Applicants have reevaluated claims 12 to 18 in light of the examiner's comments. Applicants feel that, as filed, claims 12 to 18 were directed to novel subject matter. However, to define more palpably that subject matter, these claims are amended, with claims 16 and 17 thereof cancelled.

As amended, applicants' claims approach the old and long-desired feature of "linear scalability" not to lay claim to it, which cannot be done, but to circumscribe the new mechanism through which it is accomplished by the present invention, *i.e.*, the unprecedented discovery by applicants that linear scalability in a Dean vortex producing device can be accomplished consistently and with good results by employing sequentially overlapping coils of a hollow fiber.

Method claim 12 -- upon which all other claims depend -- recites the process of "coiling" hollow fiber around a mandrel that results ultimately in sequentially overlapping coils. Method claim 12 -- although not literally reciting "linear scalability" -- recites that coiling is conducted with an eye towards the accomplishment of "substantially equivalent performance" in each coil layer. Linear scalability is further established in the claim's recitations to certain "predetermined variables". Those skilled in the art, in light of the present specification, will understand that these variables can and are preferably extrapolated from a single layer device based on the new algorithms taught in the specification. Finally, method claim 12 literally recites "dean vortices", firmly placing the subject matter of the claim in the field of dean vortex generating devices.

Any process circumscribed by the limitations of claim 12 will necessarily result in a multi-layered coiled filtration device wherein the relation between the number of coils and filtration is

linear. While "linear scalability" again is not in itself new, the accomplishment of such linearity in a coiled fiber device by the use of overlapping coils is novel. The prior art teaches against overlap. It was no small measure to proceed contrary to such established doctrine.

As prior art, the examiner cites appropriately the Belfort reference. That seminal reference realized perhaps for the first time that the formation of Dean vortices in curved hollow fibers can improve the filtration performance thereof. The reference is both well known and well regarded by applicants. Still, while the Belfort reference may teach how to produce vortex instabilities, and the advantages thereof to diminish concentration polarization, it teaches little about linear scaling.

The only instance in which scaling is mentioned in the Belfort reference is at col. 2, lines 30 to 32: *i.e.,* "The Dean vortex flow of the invention not only has similar advantages as Taylor vortex and oscillating flows but also is amenable to **scale-up**". (Emphasis added). Aside from the substantial difference[1] between "scalability" in general and "linear scalability" in particular, the suggestion is prophetic, not broadly enabling, and non-specific. There is no point in the specification to which one can infer that any particular embodiment is intended for "scale up". As stated in applicants' specification:

> [A]s with other prior art uses of flow instabilities, the Belfort patent fails to teach those of ordinary skill in the art the ability to directly scale up a lab module to a multi-layered pilot or process (manufacturing) module without requiring significant trial and error. The Belfort patent merely suggests that the invention is amenable to such scaling.

Page 2, lines 28 to 32.

The mere suggestion of scalability by the Belfort reference should not necessarily be imputed to disclose scalability in the context of a multi-layer device. Scalability, for example, could also be implemented by using several fiber coils set along parallel tracks (*i.e.*, Belfort, Fig. 4). Scalability can also be provided in a single layer device by varying fiber length. Neither approach is within applicants' interest nor -- more importantly -- encompassed by applicants' claims.

Applicants cannot argue that the Belfort reference is silent on the matter of multi-layered coiled fiber devices. It is not. Though not discussed in any great detail, two such embodiments are illustrated in Figure 14 and Figure 15, respectively. The brief text supporting these Figures is as follows:

> FIG. 14 shows another embodiment of the invention where the wound coils of the membrane tubes are wound to progress both axially and radially, much like string is wound on a bobbin.
>
> FIG. 15 shows another embodiment of the invention where the membrane tube is wound to progress radially only, with each coil wound over the previous coil in the radially [sic] direction.

(Col. 10, lines 41 to 47.) The reference was reviewed thoroughly. This -- together with essentially identical text in the Brief Description of the Drawings -- is the full extent to which multi-layered coiled

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[1] "Scalable" implies simply that a device can be "predictably" enlarged, but not necessarily "linearly". It is speculated with good reason that Belfort meant the former, not the latter. Taylor-vortex producing devices -- which Belfort mentions as "prior art" -- couldn't be enlarged to an industrially feasible scale. The Belfort device could: hence, Belfort's characterization "amenable to scale up".

devices are discussed in the Belfort reference. (Applicants find it revealing that there is no indication in the text above that the embodiments of Figs. 14 and 15 are capable of linear scaling.)

If the process of determining "novelty" is nothing more than matching each element of a claim to the disclosures in a single prior art reference, then the argument that all has been disclosed by Belfort may be sound. But, this is not the law.

In addition to the "all elements" requirement, a prior art reference to be an anticipation must bear within its four corners adequate direction for the practice of the claimed invention. If the earlier disclosure offers no more than a starting point for further experiments, if its teachings will sometimes succeed and sometimes fail, if it does not inform the art without more how to practice the claimed invention, it has not correspondingly enriched the store of common knowledge and it is not an anticipation.

In the present case, there are about eight columns of text that separate the phrase "amenable to scale up" and the blurbs that identify Figs. 14 and 15. In those eight columns, there are presented numerous examples, tables, formulae, conditions, circumstances, materials, equations, dimensions, and the like, presented in detail, and applied apparently to and/or part of even larger number of potential embodiments. Applicants question then how one skilled in the art, without the benefit of applicants' work, would have so intuitively and intentionally navigated through such technical detail to connect Belfort's prophetic reference to "scale up" with his later obscure reference to Figs. 14 and 15. One skilled in the art would have had to ignore the more robustly discussed Belfort embodiments, ignore the seemingly more plausible scaling strategies of adding coils along parallel tracks and/or modulating fiber length, and ignore the common perception of the inherent non-linearity of Dean vortex formation. Even if the law would presume that such connection were made, without the benefit of applicants' algorithms -- described herein for the first time -- it remains equally questionable whether anything worthwhile could have been accomplished. It is submitted that this connection, combined with the mathematical enablement thereof, rises to the level of invention.

Finally, although not brought up by the examiner, applicants in considering the scope of their amended claims have considered the issue of inherency, particularly in light of Belfort's Figs. 14 and 15, and conclude that the claimed subject matter is not inherent in these Figures.

Although the multi-coil embodiments of Figs. 14 and 15 can be expected to produce Dean vortices throughout its coils, there is no basis for assuming it is done along "substantially equal performance parameters". After careful inspection of the formulae and calculations in the Belfort reference, not one is suitable to predetermine the variables (*e.g.*, fiber length, diameter, and angle of coiling) that lead to said equivalent performance parameters (e.g., flux), while maintaining conditions suitable for good Dean vortex formation. This is not surprising. As stated in applicants' specification:

> Dean vortices are intrinsically non-linear since the performance of a Dean vortex-producing device is inversely proportional to the radius of curvature. For multi-layered devices, the outer fiber layers necessarily have a large radius of curvature than the outer layer and therefor lower performance than the inner layers.

Page 18, lines 16 to 19. Coiling is not enough. A multi-layer wound device does not necessarily operate by means through which each layer's performance is linearly proportional.

In sum, the Belfort reference neither discloses or suggests the subject matter circumscribed by claims 12 to 18. Reconsideration and withdrawal of the rejection under Section 102 is requested.

Conclusion

The pending claims define subject matter that is neither described nor suggested by the prior art. The written description and claims meet all applicable statutory requirements. The application is in condition for allowance.

Respectfully submitted,

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RMD/--
Attachment(s):
Edited Version of Amended Claims(s), 1 page.
Pet. for 2 Mo. XOT
Corrected Declaration, 2 pages.

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Renato M. de Luna, Reg. No. 36,780
Date: June 9, 2003

EDITED VERSION OF AMENDED CLAIM(S)

12. (Amended) A method for producing a multi-layered coiled hollow fiber bundle **[that is directly scalable from a single layer coiled hollow fiber bundle, the bundles for use in separation modules]**, the method comprising <u>the steps of</u>:

[determining a performance parameter from a single layer coiled hollow fiber bundle contained in a housing and subjected to a fluid of a certain velocity such that Dean vortices are created,

determining the needed value of the variables for each additional layer so each additional layer would perform substantially equivalently to the first layer when the bundle is part of a filtration module and subjected to the fluid of the certain velocity; and

producing a multi-layered coiled hollow fiber bundle that incorporates the determined variables]

<u>(a) coiling a hollow fiber around a mandrel to form a first layer thereon, and</u>

<u>(b) coiling said hollow fiber around said mandrel over said first layer to form a second layer thereon; and</u>

<u>wherein the coiling in step (a), the coiling in step (b), and the hollow fiber satisfy predetermined variables, such that when fluid flows through said hollow fiber at a predetermined velocity, Dean Vortices are generated in the hollow fiber in both said first and second layers, and both first and second layers perform substantially equivalently along a predetermined performance parameter</u>.

13. (Amended) The method of claim 12, wherein the <u>**predetermined**</u> performance parameter is **[determined]** <u>**predetermined**</u> algorithmically.

14. (Amended) The method of claim 12, wherein the <u>**predetermined**</u> performance parameter is **[determined]** <u>**predetermined**</u> empirically.

15. (Amended) The method of claim 12, wherein **[the]** <u>**said**</u> variables **[include]** <u>**comprise**</u> the hollow fiber's outer and inner diameter, **[the number of fibers for the layer,]** the angle of coiling said **[fibers]** <u>**fiber,**</u> and the length of said **[fibers]** <u>**fiber**</u>.

18. (Amended) The method of claim 12, wherein **[the fibers are arranged so as]** <u>**said hollow fiber is coiled in both steps (a) and (b)**</u> to maximize the packing density of the <u>**hollow fiber is said**</u> fiber bundle **[in a module in which the fibers would be used]**.